NASPE CONFERENCE

Reuse of Single-Use Devices (SUDs)

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FDA's Position Historically

- Reprocessing in Hospitals/clinics (Compliance Policy Guide 300.500)
- Any Person Reprocessing a Single-use Device (SUD) Is a "Manufacturer"
- Premarket Submissions Have Not Been Requested
- Enforcement Discretion for Hospital Reprocessing

FDA's Position Historically
(continued)

- Requirements of 3rd Party Reprocessing Firms:
  - Device Registration/listing
  - Good Manufacturing Practice (GMP) Inspection
  - Medical Device Reporting
  - General Labeling Requirements
- Reuse Policy Documents & Correspondence: www.fda.gov.reuse

FDA's Developing Position

- In Two Proposed Guidance Documents (http://www.fda.gov/cdrh/reuse)
- Affects Third-party and Hospital Reprocessors Only
- Excludes Open-but-unused Single-use Devices and Pacemakers
- Requires Premaket Submission Based on Risk; 6-18 Months After Guidance Finalization
- Subjects Reprocessors to All Other Regulatory Requirements (GMP, MDR, Tracking, Labeling, Etc.)

Review Prioritization Scheme (RPS)

(Feb. 8, 2000 version)

- Describes Process Used to Categorize the Risk of Reprocessed Suds
- Assigns Overall Risk to Each SUD Using Flowcharts Showing the Risk of Infections and the Risk of Inadequate Performance Following Reprocessing
- Provides a List of Frequently Reprocessed Devices Identifying Their Classification (Class I, II or III) and Assigned Risk

RPS (continued)

- Three Classes of Risk:
  - High
  - Moderate
  - Low

High-Risk SUDs

- 510(k) or PMA Within 6 Months After Issuance of Final FDA Enforcement Guidance.
- Submission Must Be of Sufficient Quality So That FDA Can Perform Substantive Review
- Reprocessor Must Receive SE or Approval to Market Device Within 6 Months of Filing Deadline

Moderate-Risk SUDs

- Must Submit 510(k) or PMA Within 12 Months of Issuance of Final Enforcement Sguidance
- Submission Must Be of Sufficient Quality So That FDA Can Perform Substantive Review
- Reprocessor Must Receive SE or Approval to Market Device Within 6 Months of Filing Date

Low-Risk Devices

- 510(k) or PMA Submitted Within 18 Months of Issuance of Final Enforcement Guidance
- 510(k) or PMA Must Be of Sufficient Quality So That FDA Can Perform Substantive Review
- Reprocessor Must Receive SE or Approval to Market Device Within 6 Months of Filing Date

Electrophysiology Catheters

- Single-use Diagnostic and Ablation Catheters
- Reprocessed for Over 10 Years
- High Risk Under Review Prioritization Guidance; 6-month Requirement
- Diagnostic _____ Class II
  Ablation _____ Class III
- FDA Identifying Premarket Submission Requirements

Where Is FDA Going From Here?

- FDA Reviewing All Comments to Proposed Guidances; Plan to Finalize in July 2000
- Considering Other Options for Use of Risk Prioritization Scheme
- Evaluating Partnership Possibilities With JCAHO; Others May Be Considered Also
- Planning Extensive Outreach Activities for Hospitals

Where Is FDA Going From Here? (continued)

- Requesting Additional Resources for Implementation
- Encouraging the Development of Standards for This Practice.
- Other Types of Reprocessors Will Be Considered Later